

Amend 17 Cal. Code of Regs. section 100090 to read:

**§ 100090. ~~Additional Requirements~~ Special Considerations for CIRM-Funded  
Procurement, Derivation and Transplantation.**

(a) Where CIRM funds are to be used for research intended to derive a covered stem cell line ~~from human gametes, embryos, somatic cells or tissue~~, the SCRO committee must determine or the designated institutional official must certify the applicable requirements of Code of California Regulations, title 17, section 100080, subdivision (a)(2) ~~or (a)(3)~~, have been met; subject to the following: For CIRM-funded derivation occurring after November 22, 2006, the SCRO committee must also confirm that donors provided voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100, subdivision (b).

~~(1) For embryos created on or before August 13, 2008, “valuable consideration” does not include payments to gamete donors in excess of “permissible expenses,” provided the embryo was originally created for reproductive purposes.~~

~~(2)~~ (1) For embryos created before November 22, 2006 consent exclusively from oocyte donors is sufficient provided the sperm donor cannot be identified and the donation was made in accordance with the legal requirements in force at the place and time of donation.

(2) For gametes or embryos, procured from human subjects, after November 22, 2006, the SCRO committee must confirm that donors provided voluntary and informed consent in accordance with Code of California Regulations, title 17, section 100100, subdivision (b).

**Optional subdivision:**

(3) For research involving the use of embryos originally created using in vitro

1 fertilization for reproductive purposes, the physician performing oocyte retrieval or  
2 attending physician responsible for infertility treatment may not be the CIRM-funded  
3 Principal Investigator (as defined in tile 17, California Code of Regulations, section  
4 100500) unless the SCRO has approved an exemption from this requirement.

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7 ~~(b) California Code of Regulations title 17, section 100090(a), does not apply to CIRM-~~  
8 ~~funded research intended to derive a covered stem cell line from somatic cells when the SCRO~~  
9 ~~committee has determined the requirements of California Code of Regulations title 17, section~~  
10 ~~100080, subdivisions (a)(3)(A) and (a)(3)(B), have been met. Where a covered stem cell line is~~  
11 ~~derived from~~

12 (4) For human somatic cells, procured from human subjects after November 22, 2006,  
13 and the CIRM-funded research is designed to develop cells for transplantation into a live born  
14 human, the SCRO committee must confirm that donors provided voluntary and informed consent  
15 including the requirements of Code of California Regulations, title 17, section 100100,  
16 subdivision (b)(1)(E).

17 (b) CIRM funds may not be use to provide valuable consideration to donors of gametes,  
18 embryos, somatic cells or tissue. This provision does not prohibit reimbursement for permissible  
19 expenses as defined in California Code of Regulations, title 17, section 100020, subdivision (h).

20 (c) The modification of an acceptably derived stem cell line shall not be considered a  
21 CIRM-funded derivation.

- 1 Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and
- 2 Safety Code. Reference: Sections 125290.35, 125290.40 and 125290.55, Health and Safety
- 3 Code.